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**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Docket Number (Optional)

50623.334

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Signature

Typed or printed

Name Rebecca M. Klits

Application Number

10/663,181

Filed

September 15, 2003

First Named Inventor

Stephen Z. Wu

Art Unit

1615

Examiner

Humera N. Sheikh

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the



applicant/inventor.



assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.

(Form PTO/SB/96)



attorney or agent of record.

Registration number 58,381

attorney or agent acting under 37 CFR 1.34.

Registration number \_\_\_\_\_

Signature

Jeffrey C. Talkington, Ph.D.

Typed or printed name

(415) 954-0200

Telephone number

May 24, 2007

Date

\*Total of 1 forms are submitted.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:	Examiner:
Stephen Z. Wu, et al.	Humera N. Sheikh
Serial No. 10/663,181	Art Unit: 1615
Filed: September 15, 2003	
Title: Microparticle Coated Medical Device	

Mail Stop AF  
Commissioner for Patents  
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Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Claims 25-33 are pending and have been twice rejected. Review of the rejections in this application is respectfully requested since the Examiner has ignored the legal requirements of a *prima facie* case of obviousness.

Claims 25-33 have been twice rejected for obviousness over WO 01/01890 A1 to Yang et al.

Yang discloses medical devices having polymeric coatings containing therapeutic agents. The therapeutic agents are applied to a stent as a polymeric "surface treatment" that is accomplished through "either a dipping or spraying process." (p. 7, lines 18-20, Yang) In both methods, "a solvent carrier" is used to incorporate "the therapeutic agent within the polymer matrix." (p. 7, lines 19-20, Yang) The "applied mixture preferably comprises a solvent, a polymer, and a therapeutic agent, with subsequent evaporation of the solvent to leave a polymeric coating." (p. 7, lines 20-23, Yang)

Claim 25 reads "...adding polymeric particles containing a therapeutic substance to a fluid form of an implantable medical device coating material... and solidifying the coating material to a film layer wherein the film layer includes the polymeric particles containing the therapeutic substance."

One criterion of a *prima facie* case of obviousness is that the combined references teach or a modified prior art reference teaches or suggests all claim limitations. MPEP 2143. Yang fails to teach or suggest all the limitations of claim 25.

First, Yang does not teach or suggest, expressly or inherently, adding polymeric particles containing a therapeutic substance to a fluid form of a coating material.

Second, there is no teaching or suggestion in Yang that the polymeric coating that is formed includes polymeric particles containing a therapeutic substance. Additionally, even though Yang teaches that the coating can include a blend of first and second polymers, there is no teaching or suggestion that the blend includes particles of one polymer dispersed within the other.

Another one of the requirements of a *prima facie* case of obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. MPEP 2143. Indeed, “To support the conclusion that the claimed invention is directed to obvious subject matter...the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references.” *Ex parte Clapp*, 227, U.S.P.Q 972, 973

The Examiner has provided neither suggestion nor motivation for modifying the teachings of Yang nor a convincing line of reasoning as to why the claimed invention would have been obvious to one skilled in the art. The Examiner simply states that “given the explicit teachings of Yang et al., the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.”

The Examiner does remark that the prior art teaches a “similar” method of coating stents. Even if Yang’s method is “similar” to Applicants’ method, which it is not, “similar” is not a criteria for a *prima facie* case of obviousness. The criteria is that the modified prior art reference must teach or suggest all the claim limitations, which Yang does not.

The Examiner considered these arguments in the Final Office Action dated March 26, 2007 finding them unpersuasive and suggesting that since Applicants had not defined

the size of the particles, that the dispersion of agent within a polymer, as suggested by Yang, made the present invention obvious.

This is not the case. Applicants are employing particles containing therapeutic agent, and the lack of a size description does not negate this. Yang, in contrast, discloses a solution of polymer and solvent with therapeutic agent dispersed throughout.

Since the Examiner has failed to establish a *prima facie* case of obviousness, claim 25, and claims 26-33 dependent thereon, are allowable.

Claims 25-32 have been twice rejected for obviousness over U.S. Patent No. 5,464,650 to Berg et al.

The Examiner states that Berg teaches "...a drug-containing expandable stent and method for making an intravascular stent by applying to the body of a stent a solution which includes a solvent, a polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent and then evaporating the solvent." Processes for preparing the coated stent are disclosed in column 3, line 52 - col. 4, line 34, wherein it is taught that a solution, which includes a solvent, polymer dissolved in the solvent and a therapeutic substance dispersed in the solvent is first prepared."

Berg fails to teach or suggest the limitations of claim 25, as set forth above with respect to Yang.

First, Berg does not teach, expressly or inherently, adding polymeric particles containing a therapeutic substance to a coating material.

Second, there is no teaching or suggestion in Berg that the polymeric coating that is formed includes polymeric particles containing a therapeutic substance.

Berg does teach coating a stent with a solution containing solvent with a therapeutic substance "dispersed in fine particles." (col. 3, line 64) In addition, Example 2 of Berg teaches dipping a stent in a "solution with suspended particles of dexamethasone." (col. 5, lines 60-61) However, there is no indication by Berg or the Examiner that a coating with polymeric particles containing therapeutic agent is formed. Thus, there is no express or inherent teaching or suggestion that the dispersed therapeutic agent is within polymer particles.

As with Yang, the Examiner stated a conclusion of a *prima facie* case of obvious without providing any support or argument for it. Furthermore, the Examiner provided no motivation or suggestion to modify Berg so that it teaches the above-mentioned claim limitations.

The Examiner considered these arguments in the Final Office Action dated March 26, 2007 finding them unpersuasive and suggesting that Berg is "suggestive" of a polymeric matrix formed in a solution that traps the drug. (Col. 5, lines 12-18) A matrix formed in solution, however, is nonsensical. The Examiner has misunderstood Berg. Berg discloses different ratios of agent and polymer in solution that affect the ability to retain the agent on the stent, not different ratios that would somehow cause a matrix, or particles, to form in solution. Regardless, Berg doesn't teach or suggest particles containing a therapeutic agent either in solution or after deposition onto the stent.

Since the Examiner has failed to establish a *prima facie* case of obviousness, claim 25, and claims 26-32 dependent thereon, are allowable.

Applicants respectfully request that claims 25-33 be considered allowable and that the application pass to issue.

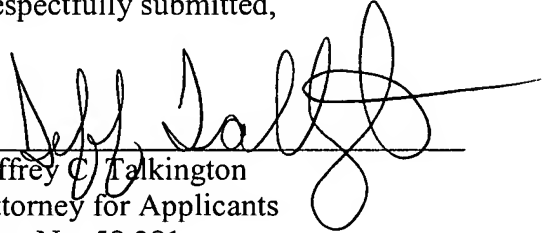
The undersigned authorizes the Examiner to charge any fees that may be required or credit of any overpayment to be made to Deposit Account No. 07-1850.

Date: May 24, 2006

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Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza  
Suite 300  
San Francisco, CA 94111  
Facsimile (415) 393-9887  
Telephone (415) 954-0230

Respectfully submitted,



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Jeffrey C. Talkington  
Attorney for Applicants  
Reg. No. 58,381